
Medicare Inpatient Prospective Payment System

Payment Rule Brief — FINAL RULE

Program Year: FFY 2021

Overview and Resources

On September 2, 2020, the Centers for Medicare and Medicaid Services (CMS) released the final federal fiscal year (FFY) 2021 payment rule for the Medicare Inpatient Prospective Payment System (IPPS). The final rule reflects the annual updates to the Medicare fee-for-service (FFS) inpatient payment rates and policies. In addition to the regular updates to wage indexes and marketbasket, this rule includes:

- A rate increase amount (+0.5%) for the Coding Offset adjustment;
- Changes to CBSA delineations;
- Updates to the Medicare Disproportionate Share Hospital (DSH) payment policies including hospitals will be eligible for DSH payments in FFY 2021 based on audited FFY 2017 S-10 data; ;
- Requiring hospitals to report the median payer-specific negotiated rates for inpatient services, by MS-DRG, for Medicare Advantage organizations on the Medicare cost report;
- Creating a new MS-DRG for CAR-T therapy;
- Updates to the program rules for the Value-Based Purchasing (VBP), Readmission Reduction Program (RRP) and Hospital-Acquired Condition (HAC) programs; and
- Updates to the payment penalties for non-compliance with the Hospital Inpatient Quality Reporting (IQR) and Electronic Health Record (EHR) Incentive Programs.

Program changes would be effective for discharges on or after October 1, 2020 unless otherwise noted. CMS estimates the overall impact of this final rule update to be increase of approximately \$3.528 billion in aggregate payments for acute care hospitals in FFY 2021. This estimate includes operating, capital, and new technology changes.

A copy of the final rule and other resources related to the IPPS are available on the CMS website at <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipp-pps-final-rule-home-page>.

Due to the resources dedicated to responding to the novel coronavirus (COVID-19) pandemic, CMS waived the 60-day delay in the effective date of the IPPS final rule. There will instead be a 30-day delay of the effective date of the final rule.

An online version of the rule is available at <https://www.federalregister.gov/d/2020-19637>.

A brief summary of the major hospital provisions of the IPPS final rule is provided below.

Note: Text in italics is extracted from the September 18, 2020 copy of the *Federal Register (FR)*.

IPPS Payment Rates

FR pages 58435, 58443 - 58445, 58796 - 58799, 58892 - 58893, and 59027 - 59049

The table below lists the federal operating and capital rates adopted for FFY 2021 compared to the rates currently in effect for FFY 2020. These rates include all marketbasket increases and reductions as well as the application of annual budget neutrality factors. These rates do not reflect any hospital-specific adjustments (e.g. penalty for non-compliance under the IQR Program and EHR Meaningful Use Program, quality penalties/payments, DSH, etc.).

	Final FFY 2020	Final FFY 2021	Percent Change
Federal Operating Rate	\$5,796.63	\$5,961.19 (proposed at \$5,979.74)	+2.84% (proposed at +3.16%)
Federal Capital Rate	\$462.33	\$466.22 (proposed at \$468.36)	+0.84% (proposed at +1.30%)

The following table provides details for the final annual updates to the inpatient federal operating, hospital-specific, and federal capital rates for FFY 2021.

	Federal Operating Rate	Hospital-Specific Rates	Federal Capital Rate
Marketbasket (MB) Update/Capital Input Price Index	+2.4% (proposed at 3.0%)		+1.1% (proposed at +1.5%)
ACA-Mandated Reductions 0.0 percentage point (PPT) productivity reduction	-0.0 PPT (proposed at -0.4 PPT)		—
MACRA-Mandated <u>Retrospective</u> Documentation and Coding Adjustment	+0.5%	—	—
Budget Neutrality Adjustments Related to FFY 2021 Wage Index Changes	-0.10% (proposed at -0.11%)		+0.21% (proposed at +0.25%)
Annual Budget Neutrality Adjustments	+0.03% (proposed at +0.15%)		-0.46% (proposed at -0.44%)
Net Rate Update	+2.84% (proposed at +3.16%)	+2.34% (proposed at +2.66%)	+0.84% (proposed at +1.30%)

- **Effects of the Inpatient Quality Reporting (IQR) and EHR Incentive Programs (FR page 58798):** Beginning in FFY 2015, the IQR MB penalty changed from -2.0 percentage points to a 25% reduction to the full MB, and the EHR Meaningful Use (MU) penalty began its phase-in over three years, starting at 25% of the full MB. Beginning FFY 2017, the EHR MU penalty has capped at 75% of the MB; hence the full MB update is at risk between these two penalty programs. A table displaying the various update scenarios for FFY 2021 is below:

	Neither Penalty	IQR Penalty	EHR MU Penalty	Both Penalties
Net Federal Rate Marketbasket Update (2.4% MB less 0.0 PPT productivity)	+2.40%			
Penalty for Failure to Submit IQR Quality Data (25% of the base MB Update of 2.4%)	—	-0.60 PPT	—	-0.60 PPT
Penalty for Failure to be a Meaningful User of EHR (75% of the base MB Update of 2.4%)	—	—	-1.80 PPT	-1.80 PPT
Adjusted Net Marketbasket Update (prior to other adjustments)	+2.40%	+1.80%	+0.60%	-0.00%

- **Retrospective Coding Adjustment (FR pages 58435, 58443 - 58445):** CMS finalized a retrospective coding adjustment of +0.5% to the federal operating rate in FFY 2021 as part of the fourth year of rate increases (of six) tied to the American Taxpayer Relief Act (ATRA). The coding offset rate increase was authorized as part of ATRA, which required inpatient payments to be reduced by \$11 billion over a 4-year period, resulting in a cumulative rate offset of approximately -3.2%.
- **Outlier Payments (FR pages 59034 – 59041):** Due to prior concerns over CMS' decision to not consider outlier reconciliation in the outlier threshold development for a given fiscal year, CMS continues to believe that using a methodology that incorporates historic cost report outlier reconciliations to develop the threshold would be a

reasonable approach and would provide a better predictor for upcoming fiscal year. Therefore, for FFY 2021, CMS will incorporate total outlier reconciliation dollars from the FFY 2015 cost reports into the outlier model.

Analysis done by CMS determined outlier payments at 5.11% of total IPPS payments; CMS is adopting an outlier threshold of \$29,051 (proposed at \$30,006) for FFY 2021. The adopted threshold is 9.74% higher than the current (FFY 2020) outlier threshold of \$26,473.

Wage Index

FR pages 58742 – 58793

CMS adopted several changes that will affect the wage index and wage index-related policies for FFY 2021 and beyond. Of most significance, CMS finalized to update the CBSA delineations, the labor-markets that define a hospital's Medicare wage index. The CBSA changes and other notable wage index-related items are detailed below:

- **CBSA Delineation Changes** (*FR pages 58743 – 58753, 58771 – 58779*): CMS' adopted changes to the CBSA delineations will have a direct impact on the Medicare wage index and other factors used for payment purposes under the IPPS. CMS last made a major update to the CBSA delineations in FFY 2015 (based on OMB Bulletin No. 13-01 using the 2010 Census). The CBSA changes adopted for FFY 2021 (based on OMB Bulletin No. 18-04, also using the 2010 Census) are not as substantial as those made in FFY 2015 in terms of changes in the geographic make-up of the labor-market areas, but would result in material changes to many hospitals. Under the new delineations there will be:
 - newly created CBSAs;
 - urban counties that become rural (*FR pages 58746 – 58748*)
 - Based on previously adopted regulations, for the first year, hospitals in these counties will receive an adjustment to DSH payments equal to 2/3rds of the difference between the prior urban DSH payments and the new rural DSH payments. In the second year following the change to rural status, these hospitals will instead receive an adjustment to their DSH payments equal to 1/3rd of the difference;
 - rural counties that become urban (*FR pages 58748 – 58750*)
 - Based on previously adopted regulations, Critical Access Hospitals (CAHs) located in these counties have two years from the date the urban redesignation takes effect to reclassify as rural in order to retain their CAH status; and
 - existing CBSAs that split apart, change in name or number, or incorporate additional counties (*FR pages 58750 - 58753*).

The new delineations will also have an effect on:

- hospital reclassifications under the MGCRB (*FR pages 58771 – 58779*)
 - CMS adopted that hospitals reclassified to CBSAs that will be split apart will be assigned to the CBSA with the most proximate county that is both located outside the hospital's final FFY 2021 geographic CBSA, and is part of the original FFY 2020 CBSA that the hospital was reclassified to. For county group reclassifications, this target county would be that which is closest to the majority of hospitals in the reclassification group.
 - If a reclassified hospital or county group wished to be reassigned to another eligible FFY 2021 CBSA (containing at least one county from the FFY 2020 CBSA to which they were reclassified), for which the hospital meets the applicable proximity criteria, the hospital was required to send this request to WageIndex@cms.hhs.gov within 45 days of the date that the proposed rule was published in the *Federal Register*. Those hospitals requesting reassignment must have provided documentation that they are eligible for this change.
 - Hospitals that become reclassified to their geographic CBSA as a result of these changes are to be assigned a "Home Area" reclassification and would receive the geographic hospital wage index value, not the reclassified hospital value for this CBSA; and
- the treatment of hospitals with Lugar status (*FR pages 58779 - 58786*);
 - For FFY 2021, CMS reevaluated Lugar status for all hospitals using the same commuting data table (2006-2010 5-Year American Community Survey Community Flows and Employment) used to determine the current list of Lugar counties.
- hospitals that reclassify as rural; and

- the applicability of the out-migration adjustment.

The finalized CBSA changes will have both positive and negative impacts on IPPS payments to hospitals. To mitigate negative impacts, CMS adopted to apply a 2-year wage index transition for **ANY** hospital that experiences a wage index decrease of at least 5% (estimated to be about 108 hospitals). This transitional adjustment would ensure that a hospital's FFY 2021 wage index value would not be less than 95% of what it was for FFY 2020, regardless of if that hospital is in a CBSA that changed. The full impact of the wage index changes would come into effect for FFY 2022. Similar to the wage index transition applied for FFY 2020, this "5% stop loss" adjustment would be budget neutral nationally and results in a 0.998015 adjustment to the IPPS operating rate for FFY 2021.

OMB Bulletin 18-04 can be found at <https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf>. The March 6, 2020 OMB Bulletin 20-01 was not issued in time for integration into the rule. This bulletin can be found at <https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf>. For FFY 2022, CMS intends to propose any updates from the OMB bulletin to further update CBSA delineation.

- **Addressing Wage Index Disparities between High and Low Wage Index Hospitals (FR pages 58765 – 58768):** CMS had noted that many comments from the Wage Index RFI in the FFY 2019 IPPS proposed rule reflected "*a common concern that the current wage index system perpetuates and exacerbates the disparities between high and low wage index hospitals.*" As a result, CMS had made a variety of changes in the FFY 2020 final rule to reduce the disparity between high and low wage index hospitals.

As it was adopted to be in effect for a minimum of four years in order to be properly reflected in the Medicare cost report for future years, for FFY 2021 CMS will continue to increase the wage index for low wage index hospitals. Hospitals with a wage index value in the bottom quartile of the nation would have that wage index increased by a value equivalent to half of the difference between the hospital's pre-adjustment wage index and the 25th percentile wage index value across all hospitals. CMS will continue to offset these increases in a budget neutral manner by applying a budget neutrality adjustment to the national standardized amount. For the FFY 2021 final rule, the value of the 25th percentile wage index is 0.8465 (proposed at 0.8420), and the final net budget neutrality adjustment is 1.000943 (proposed 1.000348) after backing out the effects of the FFY 2020 adjustment.

- **Hospitals with One or Two Years of Wage Data Seeking MGCRB Reclassification (FR pages 58770 – 58771):** CMS has adopted a modification to the regulations in order to clarify that a hospital may qualify for an individual wage index reclassification to another labor market area if the hospital only has 1 or 2 years of wage data. For hospitals that have accumulated fewer than 3 years of wage data within the applicable 3-year average hourly wage period used by the MGCRB, the wage data to be used by the hospital is either the single year of published wage data (if the hospital has only 1 year of wage data), or the weighted average of its 2 years of wage data within the 3-year period reviewed by the MGCRB.

Once a hospital has at least 1 year of wage data in the applicable 3-year period used by the MGCRB, that hospital is eligible to apply for reclassification; hospitals without wage data or that have accumulated less than 1 year of wage data would not be eligible for individual wage index reclassification. Due to the COVID-19 PHE, CMS extended the deadline for hospitals to apply for FFY 2022 reclassification to 15 days after the public display date of the FFY 2021 IPPS final rule.

- **CY 2019 Occupational Mix Survey (FR page 58762):** CMS states that the FFY 2022 wage index calculation will utilize the CY 2019 Occupational Mix Survey. Hospitals were originally required to submit their completed 2019 surveys to their MACs by July 1, 2020; however, due to COVID-19, CMS granted an extension until September 3, 2020. The preliminary survey data was released on September 8, 2020 and any revision was due by September 10, 2020. The Occupational Mix survey data can be found at <https://www.cms.gov/files/zip/fy-2022-preliminary-september-occupational-mix-puf.zip>.
- **Urban to Rural Reclassification (FR pages 58787 – 58788):** Currently, hospitals wishing to appeal MGCRB reclassification decisions (i.e. a request for Administrator review) for an urban to rural reclassification must mail the application to the CMS Hospital and Ambulatory Policy Group, and not submit through fax or other electronic means. CMS is adopting the elimination of this restriction and thus would allow these applications to be submitted by mail, fax, or other electronic methods.

This is similar to the change adopted for FFY 2020 wherein hospitals that wished to apply for an urban to rural reclassification are now allowed to submit these applications by mail, fax, or other electronic methods.

- **Labor-Related Share (FR pages 58792 – 58793):** The wage index adjustment is applied to the portion of the IPPS rate that CMS considers to be labor-related. For FFY 2021, CMS will continue applying a labor-related share of 68.3% for hospitals with a wage index of more than 1.0. By law, the labor-related share for hospitals with a wage index less than or equal to 1.0 will remain at 62%.

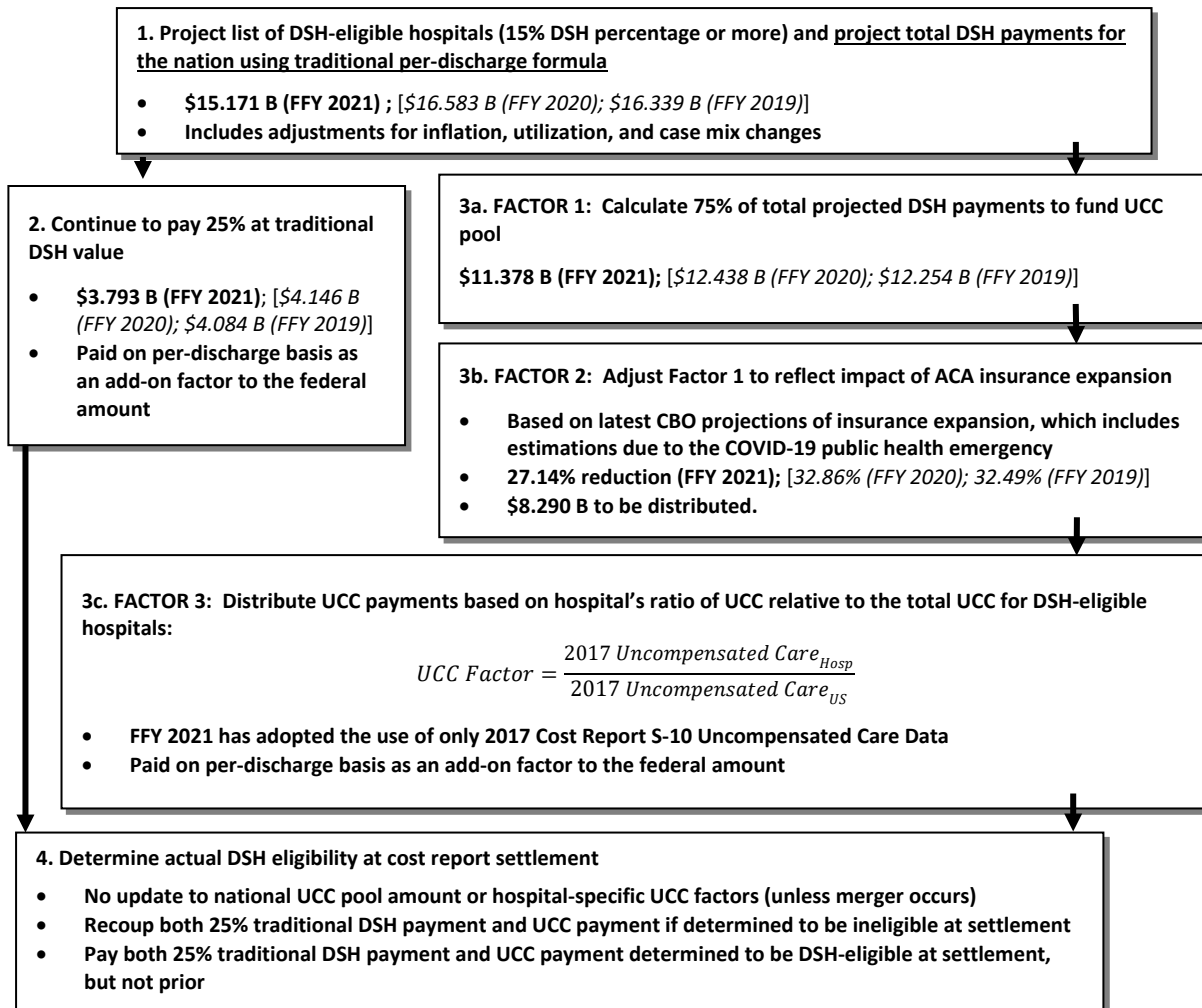
A complete list of the final wage indexes for payment in FFY 2021 is available on Table 2 on the CMS Web site at <https://www.cms.gov/files/zip/fy-2021-ippes-fr-tables-2-3-4a-4b.zip>

DSH Payments

FR pages 58804 – 58835 and 59076 – 59079

The ACA mandates the implementation of Medicare DSH calculations and payments in order to address the reductions to uncompensated care as coverage expansion takes effect. By law, 25% of estimated DSH funds, using the traditional formula, must continue to be paid to DSH-eligible hospitals. The remaining 75% of the funds, referred to as the Uncompensated Care (UCC) pool, are subject to reduction to reflect the impact of insurance expansion under the ACA. This UCC pool is to be distributed to hospitals based on each hospital’s proportion of UCC relative to the total UCC for all DSH-eligible hospitals.

- **DSH Payment Methodology for FFY 2021 (FR pages 58804 – 58835):** The following schematic describes the DSH payment methodology mandated by the ACA along with how the program has been finalized to change from FFY 2020 to FFY 2021:



The DSH dollars available to hospitals under the ACA’s payment formula will decrease by \$60 million (proposed at \$534 million) in FFY 2021 relative to FFY 2020 due to a decrease in the pool from projected DSH payments.

- **Eligibility for FFY 2021 DSH Payments (FR pages 58805 – 58806 and 59076 – 59078):** CMS is projecting that 2,401 hospitals will be eligible for DSH payments in FFY 2021 based on audited FFY 2017 S-10 data. Only hospitals identified in the final rule as DSH-eligible will be paid as such during FFY 2021. CMS has made a file available that includes DSH eligibility status, UCC factors, payment amounts, and other data elements critical to the DSH payment methodology. The file is available at <https://www.cms.gov/files/zip/fy-2021-ippms-medicare-dsh-supplemental-data-file.zip>.
- **Adjustment to Factor 3 Determination (FR pages 58814 – 58835):** For FFY 2020, CMS began utilizing a single year of Medicare cost report data from the audited FFY 2015 S-10 Worksheet, and to not continue the three year averaging process for Factor 3.

For FFY 2021, CMS adopted the use of a single year of Worksheet S–10 data from the audited FFY 2017 cost reports to calculate Factor 3 for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals.

For the values provided with the FFY 2021 IPPS final rule, CMS utilized a HCRIS extract updated through June 30, 2020, except where report upload discrepancies by CMS or the MACs have been corrected. CMS intends to use March updates for all future final rules but will revisit the topic in future rulemaking.

CMS adopted for FFY 2022 and all subsequent fiscal years, to use the most recent single year of cost report data that has been audited for a significant number of hospitals receiving substantial Medicare uncompensated care payments to calculate Factor 3 for all eligible hospitals, with the exception of hospitals located in Puerto Rico and Indian Health Service and Tribal hospitals. CMS will consider the issues raised regarding these providers in future rulemaking.

For FFY 2021 and forward, CMS adopted the modification of the current calculation for determining the uncompensated care values for when hospitals merge. Specifically, when the effective date of the merger occurs partway through the surviving hospital’s cost reporting period, to more accurately estimate UCC for the hospitals involved in a merger, CMS will not annualize the acquired hospital’s data. In addition, CMS adopted the use of *“only the portion of the acquired hospital’s unannualized UCC data that reflects the UCC incurred prior to the merger effective date, but after the start of the surviving hospital’s current cost reporting period.”*

CMS adopted the modification to its current policy for FFY 2021 and subsequent years when a hospital has a cost report that starts in one fiscal year but spans the entirety of the following fiscal year such that the hospital has no cost report starting in that subsequent fiscal year. In these situations, CMS would use the annualized cost report that spans both fiscal years for purposes of calculating Factor 3 when data for the latter fiscal year is used in the Factor 3 methodology.

For FFY 2021, CMS finalized the continuation of its new hospital methodology such that any hospitals with a CCN created on or after October 1, 2017, due to the lack of FFY 2017 cost report data, these hospitals will not receive interim FFY 2021 DSH UCC payments. However, CMS states that the MACs will make final determinations as to DSH eligibility for these hospitals at cost report settlement and, if eligible, they shall receive UCC payments using a Factor 3 based on their FFY 2021 cost report S-10 data as the numerator, set over the established national value for the FFY 2017 cost report S-10 data as the denominator.

In order to account for hospitals that consistently report very high uncompensated care values on Worksheet S-10, CMS is continuing its trimming methodology targeting the cost to charge ratio (CCR), with the exception that CMS will exclude hospitals with audited FFY 2017 cost reports from the trimming methodology.

Regarding hospitals for which CMS has elected to not use S-10 data in the past:

- **All-Inclusive Rate Hospitals:** For all-inclusive rate hospitals, which had previously been exempt from the S-10 version of Factor 3, CMS has determined that the trim methodology will mitigate any aberrant CCRs. As a result, for FFY 2020 CMS had determined these hospitals’ Factor 3 values using the audited FFY 2015 S-10 data, combined with the CCR trim methodology, which excluded these hospitals. For FFY 2021, CMS continues to believe that all-inclusive rate hospitals should be excluded from the calculation of the

statewide CCR values used for the trim. However, CMS adopted its adjustment to the UCC trim methodology for when it is applied to all-inclusive rate hospitals so that when such a hospital's total FFY 2017 UCC is greater than 50% of its total operating costs (when calculated using the CCR reported on Worksheet S-10, line 1 of its FFY 2017 cost report), CMS would recalculate that UCC using the CCR of the hospital's most recent available prior year cost report that would not also result in UCC of over 50% of total operating costs.

- **UCC Distributions for Indian Health Service (IHS) and Tribal Hospitals:** CMS will continue to not utilize Worksheet S-10 for the calculation of Factor 3 for IHS/Tribal hospitals. Instead, Factor 3 amounts for these providers will be calculated by utilizing the FFY 2013 data for Medicaid days, due to the effects of Medicaid expansion on data reported for FFYs 2014 and 2015, which would then combined with the most recent update of the SSI days. The denominator for these hospitals' Factor 3 determination would continue to be based on low-income patient days.

In addition, for FFY 2022 CMS will continue to seek comments on the following:

“Given the unique nature of IHS and Tribal hospitals, and the fact that we do not believe that the DSH analysis available to Congress at the time section 3133 of the Affordable Care Act was being developed was focused on the specific circumstances of these hospitals, we believe it may be appropriate, beginning in FY 2022... to create an exception for IHS and Tribal hospitals from Medicare DSH payments... This exception would also have the consequence that IHS and Tribal hospitals would be excluded from the calculation of Medicare uncompensated care payments... Concurrently, we believe it may be appropriate to use our authority... to adjust payments to IHS and Tribal hospitals through the creation of a new IHS and Tribal hospital Medicare DSH payment.

The methodology for determining this IHS and Tribal hospital Medicare DSH payment would mirror the calculation of the Medicare DSH payment... except that the payment would be determined at 100 percent of the calculated amount rather than 25 percent of the calculated amount as required under section 3133 of the Affordable Care Act.”

- **UCC Distributions for Puerto Rico Hospitals:** For Puerto Rico hospitals, CMS had considered calculating their FFY 2021 Factor 3 amounts using the same methodology finalized for hospitals excluding IHS and Tribal hospitals. However, due to the potential for the recent natural disasters in Puerto Rico to negatively impact these hospitals' ability to engage in FFY 2021 rulemaking, while also focusing on ensuring that their FFY 2018 Worksheet S-10 data is accurate for use in FFY 2022, CMS chose not to make this proposal for FFY 2021.

For FY 2021, CMS will determine Factor 3 for Puerto Rico hospitals based on FFY 2013 Medicaid days and the most recent update of SSI days, with a denominator based on low-income patient days. In addition, as residents of Puerto Rico are not eligible for SSI benefits, CMS will continue to use a proxy for SSI days for Puerto Rico hospitals, consisting of 14 percent of a hospital's Medicaid days.

CMS will continue to use a hospital's three-year average discharge number to estimate their uncompensated care payment per discharge. As in past years, interim payments made using this value will be reconciled at cost report settlement to equal the uncompensated care pool distribution amount that will be published with the FFY 2021 IPPS final rule.

Due to a comment on the FFY 2020 IPPS proposed rule that expressed concern that discharge growth discrepancies create the risk of overpayments and unstable cash flows, for FY 2021, CMS is adopting that a hospital may elect to submit a request to its MAC for a lower per discharge interim uncompensated care payment amount, once before the beginning of the Federal fiscal year and/or once during the Federal fiscal year. With this request a hospital would be required to provide supporting documentation that showed the likelihood of significant recoupment at cost report settlement if the per discharge amount were not lowered. This would not change the total amount of uncompensated care payments received by the hospital for the year.

For FY 2021, CMS finalized that hospitals would have 15 business days from the date of public display of the FFY 2021 IPPS/LTCH PPS final rule to review and submit comments on the accuracy of the table and supplemental data file published along with the final rule. Any changes to distribution amounts will be posted on the CMS website prior to October 1, 2020.

GME Payments

FR pages 58803 – 58804 and 58865 – 58870

To address the needs of residents attempting to find alternative hospitals to complete their training as well as to facilitate seamless Medicare IME and direct GME funding for originating and receiving hospitals, CMS adopted two policy changes.

CMS adopted that the key day for linking temporary Medicare funding would be the day that the hospital/residency program closure was publicly announced, allowing residents time to find a new facility at which to complete their training while the residency program of the originating hospital winds down. This would be instead of the current method of linking Medicare temporary funding for the affected residents to the day prior to or the day of program or hospital closure.

CMS also adopted its proposal to allow funding to be transferred temporarily for the second and third group of residents who are not physically present at the closing hospital/closing program, but had intended to train at (or return to training at, in the case of residents on rotation) the closing hospital program.

To apply for the temporary Medicare resident cap increase, the receiving hospital must submit a letter to its MAC within 60 days of beginning the training of the displaced residents (residents added by a receiving hospital due to a hospital or program closure whom have not yet started training at the closing hospital or program). However, CMS will only require the last four digits of each resident's social security number or their National Provider Identification (NPI) number to reduce the amount of personally identifiable information included in the letter.

The Indirect Medical Education (IME) adjustment factor will remain at 1.35 for FFY 2021.

Updates to the MS-DRGs

FR pages 58843 – 58742, 58793 – 58796, 58835 – 58842, and 58873 – 58893

Each year CMS updates the MS-DRG classifications and relative weights to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Changes adopted for FFY 2021 MS-DRGs leave the total number of payable DRGs at 765. 81% of DRG weights will change by less than +/- 5%, and 5% change by +/- 10% or more. The five MS-DRGs with the greatest year-to-year change in weight are:

MS-DRG	Final FFY 2020 Weight	Final FFY 2021 Weight	Percent Change
MS-DRG 295: DEEP VEIN THROMBOPHLEBITIS WITHOUT CC/MCC	0.5770	0.9813	+70.1%
MS-DRG 796: VAGINAL DELIVERY WITH STERILIZATION/D&C WITH MCC	1.9723	1.0679	-45.9%
MS-DRG 933: EXTENSIVE BURNS OR FULL THICKNESS BURNS WITH MV >96 HRS WITHOUT SKIN GRAFT	3.1402	2.2576	-28.1%
MS-DRG 819: OTHER ANTEPARTUM DIAGNOSES WITH O.R. PROCEDURE WITHOUT CC/MCC	0.7979	0.9979	+25.1%
MS-DRG 114: ORBITAL PROCEDURES WITHOUT CC/MCC	1.1908	1.4455	+21.4%

When CMS reviews claims data, they apply the following criteria to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within an MS-DRG is needed, a subgroup must meet all five criteria in order to warrant being created:

- a 3% reduction in the variance of costs;
- at least 5% of patients in the MS-DRG fall within the subgroup
- 500 or more cases are in the subgroup;
- average costs between the subgroups show at least a 20-percent difference; and
- there is a \$2,000 difference in average costs between subgroups.

Beginning with FFY 2021 CMS is expanding these criteria to also include Non-CC subgroups with the belief that this would better reflect resource stratification and promote stability of MS-DRG relative weights by avoiding low volume counts for the Non-CC level MS-DRGs.

The full list of final FFY 2021 DRGs, DRG weights, and flags for those subject to the post-acute care transfer policy are available in Table 5 on the CMS website at <https://www.cms.gov/files/zip/fy-2021-ipps-fr-table-5.zip>.

For comparison purposes, the FFY 2020 DRGs are available in Table 5 on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2020-FR-Table-5.zip>.

- **Chimeric Antigen Receptor (CAR) T-Cell Therapies** (FR pages 58451 – 58453, 58599 – 58872, and 58842 – 58844): CAR T-cell treatments are eligible for new technology add-on payments for FFY 2020. There had been a request to create a new MS-DRG specifically for CAR T-cell treatments, however CMS did not make any changes for FFY 2020 due to the limited number of cases in which they are used, and as a result would have made the creation of a CAR T-cell therapy-specific MS-DRG appear premature.

In the FFY 2020 proposed rule, CMS had sought public comment on payment alternatives for CAR-T cell therapies in response to the following topics:

- the most appropriate method to use to develop a relative weight should CMS propose a CAR T-cell therapy MS-DRG in the future;
- to what extent it would be appropriate to apply the wage index to such an MS-DRG as CMS's understanding of the therapy is that the costs do not vary among geographic areas;
- if IME and DSH adjustment add-on percentages should be reduced for these treatments due to their already high payments;
- elimination of the use of CCR in calculating new technology add-on payments for the existing CAR T-cell treatments, by making the add-on payment amount capped at 65% of the marginal cost of the technology, vs. the current 50%; and
- if CMS should consider using a specific CCR for ICD-10-PCS procedure codes used to report the performance of procedures involving CAR T-cell therapies.

Now that CMS has more data for cases involving CAR T-cell therapies, CMS believes that it is appropriate to consider development of a new MS-DRG. For FFY 2021, CMS is assigning cases reporting ICD-10-PCS procedure codes XW033C3 or XW043C3 to a new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), and to remove those codes from MS-DRG 016 and rename it "Autologous Bone Marrow Transplant with CC/MCC". As additional procedure codes for CAR-T cell therapies are created, CMS will use its established process to assign these procedure codes to the most appropriate MS-DRG.

A large percentage of the cases that would group to the new MS-DRG for CAR T-cell therapy would be *"clinical trial cases, in which the provider typically does not incur the cost of the drug. By comparison, for non-clinical trial cases involving CAR T-cell therapy, the drug cost is an extremely large portion of the total costs."* As a result, CMS adopted a modification to its relative weight methodology for MS-DRG 018 to make its relative weight reflective of the typical costs of providing CAR T-cell therapies by excluding clinical trial claims from the calculation of the average cost.

As providers do not typically pay for the cost of a drug for clinical trials, CMS will apply an adjustment to the payment amount for clinical trial cases that would group to MS-DRG 018. CMS will apply an adjustment of 0.17 (proposed at 0.15) to the payment amount for clinical trial cases that would both group to MS-DRG 018 and include ICD-10-CM diagnosis code Z00.6, contain standardized drug charges of less than \$373,000, or when there is expanded access use of immunotherapy. CMS also finalized that this payment adjustment will not be applied for payment of a case where a CAR T-cell therapy product is purchased but the case involves a clinical trial of a different product. Further, CMS will apply this payment adjustment to a case where there is expanded use of immunotherapy.

- **Hip and Knee Joint Replacements** (FR pages 58491 – 58502): CMS has noted that clinically effective treatment of patients undergoing hip replacement following hip fracture tends to have greater resource requirements than

those without hip fracture. This is in addition to increased complexity associated with hip fracture patients that can be attributed to other factors related to replacement due to bone fracture, as well as potentially being frailer on average than those requiring hip replacement because of degenerative joint disease.

As a result, for FFY 2021, CMS is creating two new MS-DRGs for hip replacement with a principal diagnosis of hip fracture:

- MS-DRG 521: Hip Replacement with Principal Diagnosis of Hip Fracture with MCC; and
- MS-DRG 522: Hip Replacement with Principal Diagnosis of Hip Fracture without MCC.

CMS also notes that the Comprehensive Care for Joint Replacement (CJR) model includes episodes triggered by MS-DRG 469 with hip fracture and MS-DRG 470 with hip fracture. Since the CJR model was extended to at least March 31, 2021, CMS intends to incorporate MS-DRG 521 and 522 into this model as of their effective dates.

- **New Technology** (*FR pages 58602 – 58742*): CMS states that numerous new medical services or technologies are potentially eligible for add-on payments outside the PPS. In this final rule, CMS is adopting:
 - The discontinuation of add-on payments for eight medical services/technologies; and
 - The continuation of new technology add-on payments for ten technologies.

CMS sought public comment on the implementation of new technology add-on payments for a number of additional medical services/technology. Comments and responses can be found on *FR* pages 58620 – 58721.

Additionally, in FFY 2020, CMS adopted an alternative pathway for new technology add-on payments related to antimicrobial products that have been designated as a Qualified Infectious Disease Product (QIDP) by the FDA. For FFY 2022 and subsequent years, CMS adopted the expansion of this pathway to those product that have been approved as for the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) as well.

Finally, beginning with applications submitted for new technology add-on payments for FFY 2022, CMS finalized a process to grant conditional approval for new technology add-on payments for those that meet the new technology add-on payment criteria under the alternative pathway for QIDPs or LDAP, even if it has not yet received FDA marketing authorization by July 1 (the existing deadline by which it must be granted FDA marketing authorization to be eligible for new technology add-on payment) of the fiscal year for which the applicant is applying for the add-on payments.

- **MS-DRG Post-Acute Care Transfer and Special Payment Policies** (*FR pages 58445 – 58588, 58793 – 58796, and 58842 – 58845*): When a patient is transferred from an acute care facility to a post-acute care or hospice setting, the transferring hospital receives a per diem payment, with a total payment capped at the full MS-DRG amount. For MS-DRGs subject to the post-acute care transfer policy that CMS deems to be high cost, CMS applies a special payment methodology so that the transferring hospital receives 50% of the full MS-DRG payment plus a per diem payment, with total payment capped at the full MS-DRG amount. Each year CMS, using established criteria, reviews the lists of MS-DRGs subject to the post-acute care transfer policy and special payment policy status.

Effective FFY 2021, CMS has adopted changes to a number of MS-DRGs affected by these policies, including:

- *“Reassign procedure codes from MS-DRG 16 (Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy) to create new MS-DRG 18 (Chimeric Antigen Receptor [CAR] T-cell Immunotherapy) for cases reporting the administration of CAR T-cell therapy.*
- *Create new MS-DRG 019 (Simultaneous Pancreas and Kidney Transplant with Hemodialysis).*
- *Reassign procedures involving head, face, neck, ear, nose, mouth, or throat by creating six new MS-DRGs 140-142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) and 143-145 (Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and deleting MS-DRGs 129-130 (Major Head and Neck Procedures with CC/MCC or Major Device, and without CC/MCC, respectively, MS-DRGs 131-132 (Cranial and Facial Procedures with CC/MCC and without CC/MCC, respectively) and MS-DRGs 133-134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with CC/MCC and without CC/MCC, respectively).*
- *Reassign procedure codes from MS-DRGs 469-470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement, and without MCC, respectively) and create two new MS-DRGs, 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC and without MCC, respectively) for cases reporting a hip replacement procedure with a principal diagnosis of a hip fracture.*

- *Reassign procedure codes from MS-DRG 652 (Kidney Transplant) into two new MS-DRGs, 650 and 651 (Kidney Transplant with Hemodialysis with MCC and without MCC, respectively) for cases reporting hemodialysis with a kidney transplant during the same admission.”*
 - Add MS-DRGs 521 and 522 to the list of post-acute care transfer policy MS-DRGs as well as to the list subject to the MS-DRG special payment methodology.
- **Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs (FR pages 58835 – 58842):** Allogeneic hematopoietic stem cell transplants involve collecting or acquiring stem cells from a healthy donor’s bone marrow, peripheral blood, or cord blood for intravenous infusion to the recipient. Currently, acquisition costs associated with these services are included in the operating costs of inpatient hospital services. IPPS payments for such acquisition services are included in the MS-DRG payments for the allogeneic hematopoietic stem cell transplants when the transplants occurred in the inpatient setting. The Further Consolidated Appropriations Act of 2020 requires for cost reporting periods beginning on or after October 1, 2020, that payment to inpatient hospitals for hematopoietic stem cell acquisition be made on a reasonable cost basis, rather than be included in operating costs.

CMS is adopting regulatory amendment to reflect this new statute by updating the regulatory language to reflect that payment to inpatient hospitals for allogeneic hematopoietic stem cell transplant be paid for their acquisition costs on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020. As the Further Consolidated Appropriations Act of 2020 requires that the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs be made in a budget neutral manner, CMS is applying a budget neutrality adjustment of 0.999848 (proposed at 0.999861) to the standardized amount to account for these payments.

Rather than adopting their proposed requirement that hospitals would formulate a standard acquisition charge for these services, CMS is instead codifying the current billing methodology of actual hematopoietic stem cell acquisition charges. Eligible providers will continue to hold their donor search and acquisition charges and use revenue code 0815 on the recipient’s transplant claim. The actual charge will be billed and paid on an interim payment basis as a “pass-through” item, using the appropriate revenue code, and converted to reasonable cost using the corresponding ancillary cost-to-charge ratios. The total ancillary costs would be then divided by 26 to determine biweekly interim payment amounts. At cost report settlement, a determination would reconcile the actual cost incurred compared to the interim payments made to the hospital.

It is also being adopted that inpatient hospitals would have to *“maintain an itemized statement that identifies the services furnished in collecting hematopoietic stem cells, the charges, the person receiving the service... and the recipient’s health care insurance number.”* Also that the *“hospital’s Medicare share of the hematopoietic stem cell acquisition costs is based on the ratio of the number of its allogeneic hematopoietic stem cell transplants furnished to Medicare beneficiaries to the total number of its allogeneic hematopoietic stem cell transplants furnished to all patients, regardless of payer, applied to reasonable cost.”*

- **Market-Based MS-DRG Relative Weight Data Collection and Change in Methodology for Calculating MS-DRG Relative Weights (FR pages 58873 – 58892):** To reduce the Medicare program’s reliance on the hospital chargemaster, and support the development of a market-based approach to payment under the Medicare FFS system, CMS is adopting that hospitals be required to use the Medicare cost report to report *“the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organizations ... payers, by MS-DRG”* for cost reporting periods ending on or after January 1, 2021. Based on comments, CMS did not finalize the requirement to report charges a hospital has negotiated with all of its third-party payers.

Hospitals that only receive non-negotiated payments for service (such as IHS/Tribal or Federally-owned hospitals), CAHs, and hospitals located in Maryland would be exempted from this adopted data collection.

As hospitals are currently required to publically report payer-specific negotiated charges, CMS believes that the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals.

CMS is adopting the proposed definitions of “payer-specific negotiated charge,” “third party payer,” “MA organization,” and “items and services.”

Further, CMS adopting a new market-based methodology for estimating the MS-DRG relative weights, beginning in FFY 2024 with no transition period, which would be based on the median payer-specific negotiated charge information collected on the Medicare cost report. This methodology can be found on FR pages 59089 – 59090 of the FFY 2021 IPPS final rule.

CMS may consider additional ways to reduce the role of hospital chargemasters and to better reflect market-based approaches in Medicare IPPS payments in future rulemaking. In the proposed rule, CMS had requested comments on “*alternatives to the current use of hospital charges in determining other inpatient hospital payments, including outlier payments and new technology add-on payments, to the extent permitted by law.*” Public comments and CMS’ responses can be found on FR pages 58881 – 58891 of the FFY 2021 IPPS final rule.

Sole Community Hospitals (SCHs)

FR pages 58799 – 58799

CMS is aware of situations where a hospital’s most recent cost reporting period prior to seeking SCH classification is less than a 12 months in length. As a result, CMS is clarifying its policy to reflect that when a hospital’s cost reporting period ending prior to it applying for SCH status is for less than 12 months, the hospital’s next, most recent, 12-month or longer cost reporting period prior to the short period would be used.

Low-Volume Hospital Adjustment

FR pages 58802 – 58803

Legislative action by Congress over the past several years mandated changes to the low-volume hospital adjustment criteria, allowing more hospitals to qualify for the adjustment and modifying the amount of the adjustments. The Bipartisan Budget Act of 2018 had extended the relaxed low volume adjustment criteria (>15-road miles/ <1,600 Medicare discharges), through the end of FFY 2018. In addition, the Act included a further extension of the adjustment for FFYs 2019-2022 with a change to the discharge criteria by requiring that a hospital have less than 3,800 total discharges (rather than 1,600 Medicare discharges). The current payment adjustment formula for hospitals with between 500 and 3,800 total discharges is:

$$\text{Low Volume Hospital Payment Adjustment} = \frac{95}{330} - \frac{\text{Total Discharges}}{13,200}$$

Beginning with FFY 2023, the criteria for the low-volume hospital adjustment will return to the more restrictive levels. At that point, in order to receive a low-volume adjustment, subsection (d) hospitals would need to meet the following criteria:

- Be located more than 25 road miles from another subsection (d) hospital; and
- Have fewer than 200 total discharges (All Payer) during the fiscal year.

In order for a hospital to acquire low-volume status for FFY 2021, consistent with historical practice, CMS is finalizing its requirement that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC must receive a written request by September 15, 2020 (proposed as September 1, 2020) in order for the adjustment to be applied to payments for its discharges beginning on or after October 1, 2020. If accepted, the adjustment will be applied prospectively within 30 days of low-volume hospital determination.

Under this process, a hospital receiving the adjustment for FFY 2020 may continue to receive it without reapplying if it continues to meet the mileage and discharge criteria.

RRC Status

FR pages 58799 – 58801

Hospitals that meet a minimum case-mix and discharge criteria (as well as one of 3 optional criteria relating to specialty composition of medical staff, source of inpatients, or referral volume) may be classified as Rural Referral Centers (RRCs). This special status provides an exemption from the 12% rural cap on traditional DSH payments and special treatment with respect to geographic reclassification. Each year, CMS updates the minimum case-mix index

and discharge criteria related to achieving RRC status (for hospitals that cannot meet the minimum 275 bed criteria). The adopted FFY 2021 minimum case-mix and discharge values are available on the pages listed above.

For those hospitals seeking to qualify for initial RRC status, CMS is amending the RRC regulations in order to annualize the total number of discharges to determine a hospital's RRC eligibility if that hospital's most recent cost reporting period is not equal to 12 months. Additionally, if a hospital has multiple cost reports beginning in the same fiscal year and none are equal to 12 months, the hospital's number of discharges from the longest cost report beginning in that fiscal year would be annualized to estimate the total number of discharges.

Hospitals with High Percentage of End Stage Renal Disease (ESRD) Discharges

FR page 58844

CMS provides additional payment to hospitals for inpatient services provided to ESRD beneficiaries who receive a dialysis treatment during an inpatient stay, if the hospital has established that ESRD beneficiary discharges (excluding discharges with MS-DRGs 652, 682, 683, 684, and 685) where the beneficiary received dialysis services, make up at least 10% of its total Medicare discharges.

CMS is adopting the exclusion of the following newly finalized MS-DRGs from the total ESRD discharges used to determine a hospital's eligibility for the high ESRD discharge percentage payment:

- MS-DRG 019: Simultaneous Pancreas/Kidney Transplant with Hemodialysis;
- MS-DRG 650: Kidney Transplant with Hemodialysis with MCC; and
- MS-DRG 651: Kidney Transplant with Hemodialysis without MCC.

In addition, CMS is adopting the removal of the following MS-DRGs from the exclusion list:

- MS-DRG 652: Kidney Transplant; and
- MS-DRG 685: Admit for Renal Dialysis.

Quality-Based Payment Adjustments

FR pages 58844 – 58865

For FFY 2021, IPPS payments to hospitals will be adjusted for quality performance under the Value Based Purchasing (VBP) Program, Readmissions Reduction Program (RRP), and the Hospital-Acquired Conditions (HAC) Reduction Program. Detail on the FFY 2021 programs and payment adjustment factors are below (future program year program changes are addressed in the next section of this brief):

- **VBP Adjustment** (*FR pages 58847 – 58860*): The FFY 2021 program will include hospital quality data for 20 measures in 4 domains: safety; clinical outcomes; person and community engagement; and efficiency and cost reduction. By law, the VBP Program must be budget neutral and the FFY 2021 program will be funded by a 2.0% reduction in IPPS payments for hospitals that meet the program eligibility criteria (estimated at \$1.9 billion). Because the program is budget neutral, hospitals can earn back some, all, or more than their 2.0% reduction.

While the data applicable to the FFY 2021 VBP program is still being aggregated, CMS has calculated and published proxy factors based on the current year's (FFY 2020) program. Hospitals should use caution in reviewing these factors as they do not reflect updated performance periods/standards, nor changes to hospital eligibility.

The proxy factors published with the final rule are available in Table 16A on the CMS website at

<https://www.cms.gov/files/zip/fy-2021-ipp-16a.zip>.

CMS anticipates making actual FFY 2021 VBP adjustment factors available in the fall of 2020. Details and information on the program currently in place for FFY 2019 and FFY 2020 program are available on CMS' QualityNet website at

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772039937>.

- **Readmissions Reduction Program (RRP)** (*FR pages 58844 – 58847*): The FFY 2021 RRP will evaluate hospitals on 6 conditions/procedures: acute myocardial infarction (AMI), heart failure (HF), pneumonia (PN), chronic obstructive pulmonary disease (COPD), elective total hip arthroplasty (THA) and total knee arthroplasty (TKA), and coronary

artery bypass graft (CABG). The RRP is not budget neutral; hospitals can either maintain full payment levels or be subject to a penalty of up to 3.0%.

Hospitals are grouped into peer groups (quintiles) based on their percentage of full-benefit dual eligible patients as a ratio of total Medicare Fee-For-Service and Medicare Advantage patients during the same 3-year period as the program performance period. Hospital excess readmission ratios are compared to the median excess readmission ratio of all hospitals within their quintile for each of the 6 measures. A uniform modifier is applied such that the adjustment is budget neutral nationally.

The data applicable to the FFY 2021 RRP program is still being reviewed and corrected by hospitals, and therefore CMS did not yet post factors for the FFY 2021 program in Table 15. CMS expects to release the final FFY 2021 RRP factors in the fall of 2020.

Details and information on the RRP currently are available on CMS' QualityNet website at

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772412458>.

- **HAC Reduction Program (FR pages 58860 – 58865):** The FFY 2021 HAC program will evaluate hospital performance on 6 measures: the AHRQ Patient Safety Indicator (PSI)-90 (a composite of 10 individual HAC measures), Central Line-Associated Bloodstream Infection (CLABSI) rates, Catheter-Associated Urinary Tract Infection (CAUTI) rates, the Surgical Site Infection (SSI) Pooled Standardized Infection Ratio, Methicillin-resistant Staphylococcus Aurea (MRSA) rates, and Clostridium difficile (C.diff.) rates. The HAC Reduction Program is not budget neutral; hospitals with a total HAC Score that falls within the worst performing quartile for all eligible hospitals will be subject to a 1.0% reduction in IPPS payments. Total HAC scores are calculated by applying an equal weight to each measure for which a hospital has a score.

CMS uses a continuous z-score methodology for HAC which eliminates ties in the program and enhances the ability to distinguish low performers from top performers.

Details and information on the HAC currently are available on CMS' QualityNet website at

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774189166>.

Quality-Based Payment Policies—FFYs 2022 and Beyond

For FFYs 2022 and beyond, CMS is adopting new policies for its quality-based payment programs.

- **VBP Program—FFYs 2022 through 2025 (FR pages 58847 – 58860):** CMS has already adopted VBP program rules through FFY 2022 and some program policies and rules beyond FFY 2022. CMS is finalizing further program updates through FFY 2026, which include:
 - National performance standards for a subset of the FFYs 2023, 2025 and 2026 program measures (performance standards for other program measures for future program years will be put forward in future rulemaking).

Separately, in the August 25th COVID-19 interim final rule with comment period (IFC), CMS updated the extraordinary circumstances exception policy in response to the public health emergency so that no claims data or chart-abstracted data reflecting services provided January 1, 2020 - June 30, 2020 will be used in calculations for the VBP Program.

- **Readmissions Reduction Program (FR pages 58844 – 58847):** In order to provide greater certainty around future program performance periods, CMS is adopting an automatic adoption of performance periods beginning FFY 2023 and for all subsequent program years, unless otherwise specified.

The performance period will be the 3-year period beginning 1 year advanced from the previous program fiscal year's start of the performance period. The period for calculating dual eligibility would still correspond to the program year performance period. CMS is updating the definition of applicable period to reflect these changes.

Consistent with the plans outlined in the FFY 2020 final rule, CMS included data stratified by patient dual-eligible status for each individual measure in the confidential RRP hospital-specific reports in the spring of 2020.

In accordance with the August 25th COVID-19 IFC, no claims data reflecting services provided January 1, 2020-June 30, 2020 will be used in calculations for RRP. Therefore, the FFY 2022 RRP will only use data from July 1, 2017-December 31, 2019 for calculations.

- **HAC Reduction Program—FFY 2021 (FR pages 58860 – 58865):** In order to provide greater certainty around future program performance periods, CMS is adopting the automatic adoption of performance periods beginning FFY 2023 and for all subsequent program years, unless otherwise specified.

The performance period will be the 2-year period beginning 1 year advanced from the previous program fiscal year’s start of the performance period. CMS is updating the definition of applicable period to reflect these changes.

Separately, CMS is finalizing several changes to better align the HAC Program measure validation process with the finalized changes to IQR Program measure validation process, outlined as follows:

- CMS is adopting its proposal to remove 1st quarter and 2nd quarter 2021 data and only use 3rd quarter and 4th quarter 2020 data for FFY 2023 HAC Program measure validation. For FFY 2024+, CMS will use 4 quarters of CY data (ex: CY 2021 for FFY 2024); the data submission deadlines for chart-abstracted measures will be in the middle of the fifth month following the end of the reporting quarter.
- Additionally, CMS is reducing the total validation pool from up to 600 hospitals to up to 400 hospitals, effective with the FFY 2024 program year (for data beginning with CY 2021), by reducing the randomly selected hospital pool from up to 400 hospitals to up to 200 hospitals for validation; these will be the same hospitals as selected for validation in the IQR program and therefore reduce the total number of hospitals selected for validation across both programs by 1/3.
- Beginning FFY 2024, CMS is requiring hospitals to submit electronic files rather than CD, DVD, or flash drives containing digital images of patient charts as medical record submissions for validation. Hospitals will be required to submit PDF copies of medical records using direct electronic files submission via a CMS-approved secure file transmission process. CMS will continue to reimburse hospitals at \$3.00 per chart.

Adopted in the August 25th COVID-19 IFC, no claims and chart-abstracted data reflecting services provided January 1, 2020 - June 30, 2020 will be used in calculations for the HAC Reduction Program. Some data reporting has been made optional as well. Please refer to CMS-3401-IFC for details.

Updates to the IQR Program and Electronic Reporting Under the Program

FR pages 58926– 58959

CMS did not finalize any new measures for the IQR Program in this final rule.

Currently, hospitals are required to report one, self-selected calendar quarter of data for four self-selected eQMs. In the FFY 2020 final rule, CMS finalized that for CY 2022 reporting period (FFY 2024 payment determination), hospitals must report on Safe Use of Opioids – Concurrent Prescribing eQCM as one of the four required eQMs.

In order to produce more complete and accurate quality measure data for patients and providers, CMS is adopting its proposal to progressively increase, over a 3-year period, the number of quarters for which hospitals are required to report eQCM data up to four quarters of data. Until hospitals are required to submit 4 calendar quarters of self-selected data, the quarters chosen can either be consecutive or nonconsecutive. The transition is outlined below.

Reporting Period/Payment Determination	Finalized # of Self-Selected Calendar Quarters Required	Finalized # of Self-Selected eQMs required
CY 2021 reporting period/FFY 2023 payment determination	2	4
CY 2022 reporting period/FFY 2024 payment determination	3	3 and Safe Use of Opioids eQCM

CY 2023 reporting period/FFY 2025 payment determination	4	
---	---	--

In the CY 2021 Payment Policies Under the Physician Fee Schedule Proposed Rule published August 17, 2020, CMS proposed to expand flexibility under Hospital IQR Program by allowing hospitals to use either technology certified to the 2015 Edition criteria for CEHRT as was previously finalized for reporting eCQMs and for reporting hybrid measures, or technology certified to the 2015 Edition Cures Update standards as finalized in the 21st Century Cures Act.

In addition, CMS is adopting its proposal to begin publically reporting eCQM data beginning with the CY 2021 reporting period/FFY 2023 payment determination to promote transparency and reporting accuracy. CMS expects this data could be available to the public as early as fall 2022 (where there will be two quarters of data per CMS' finalized policy). Hospitals will have the opportunity to review their data before they are made public.

Separately, CMS is adding EHR Submitter ID to the required list of key elements for Quality Reporting Document Architecture Category I file identification. For vendors, the EHR Submitter ID is the Vendor ID; for hospitals, the EHR, Submitter ID is the hospital's CCN. The other key elements are: CMS Certification Number (CCN); CMS Program Name; EHR Patient ID; and Reporting period specified in the Reporting Parameters Section per the CMS Implementation Guide for the applicable reporting year.

CMS is also adopting its proposal to combine the validation process for chart-abstracted measure data and eCQM data using the following incremental approach:

- *Update the quarters of data required for validation for both chart-abstracted measures and eCQMs;*
- *Expand targeting criteria to include hospital selection for eCQMs;*
- *Change the validation pool from 800 hospitals to 400 hospitals;*
- *Remove the current exclusions for eCQM validation selection;*
- *Require electronic file submissions for chart-abstracted measure data;*
- *Align the eCQM and chart-abstracted measure scoring processes; and*
- *Update the educational review process to address eCQM validation results.*

Tables in the final rule on FR pages 58928 – 58931 outline the previously adopted Hospital IQR Program measure set for the FFYs 2022 – 2024 payment determination and subsequent years.

In the CY 2021 OPPTS/ASC proposed rule, CMS proposed to modify the methodology used to calculate the Overall Hospital Quality Star Rating. The Overall Star Rating would continue to use data collected on hospital inpatient and outpatient measures that are publicly reported on Hospital Compare or its successor site through CMS quality programs, including data from the Hospital IQR Program.

IPPS-Excluded Hospital Policies

FR pages 58893 – 58896 and 59048 – 59049

Certain hospitals excluded from the IPPS, including critical access hospitals (CAHs), children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per-discharge limit is set for each hospital based on the hospital's own cost experience in its base year, and updated annually. For FFY 2021, CMS is making the following policy changes that would affect hospitals excluded from the IPPS:

- **FFY 2021 Payment Rate of Increase for Excluded Hospitals (FR pages 58893 – 58896 and 59048 – 59049):** For each cost reporting period, an excluded hospital's updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. CMS uses the percentage increase in the IPPS operating market basket to update the target amounts for long-term care neoplastic disease hospitals, children's hospitals, cancer hospitals, and religious nonmedical health care institutions (RNHCIs), and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

For FFY 2021, CMS is setting the rate-of-increase update percentage at 2.4 percent.

Promoting Interoperability Program

FR pages 58966 – 58977

The Medicaid Promoting Interoperability Program is ending CY 2021 and therefore December 31, 2021 is the last date that States can make program incentive payments to Medicaid eligible hospitals (other than pursuant to a successful appeal related to 2021 or a prior year).

For the Medicare Promoting Interoperability Program, CMS is adopting the continuation of an EHR reporting period minimum of any continuous 90-day period for CY 2022 for new and returning participants.

For FFY 2021, the Query of Prescription Drug Monitoring Program (PDMP) measure will remain optional and worth 5 bonus points in order to give hospitals time to further progress on EHR-PDMP efforts while still providing an opportunity for those who are capable to receive points for this measure.

In additional, CMS is finalizing its proposal to replace the word “incorporating” in the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure with “reconciling” to better reflect the measure numerator calculation.

Adopted Performance-Based Scoring Methodology Beginning with EHR Reporting Periods in CY 2021:

Objectives	Measures	2021: Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Query of Prescription Drug Monitoring Program (PDMP) (finalized as optional with yes/no response)	5 point (bonus)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information*	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Choose two measures: Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Result Reporting	10 points

Measures with name changes are denoted with an asterisk ().

Consistent with the Hospital IQR program, CMS is adopting to progressively increase, over a 3-year period, the number of quarters for which hospitals are required to report eCQM data up to four quarters of data. Specifically, CMS will require 2 self-selected calendar quarters of data from CY 2021, 3 quarters from CY 2022, and 4 quarters beginning with CY 2023. In addition, CMS is adopting its proposal to start publically reporting this data beginning with the CY 2021 reporting period. The submission period for the Medicare Promoting Interoperability Program would be the 2 months following the close of the respective calendar year. More detail is included in the Hospital IQR section of this brief.

Specific to the Promoting Interoperability Program, CMS notes the issued hardship exception extension several times in this section of the final rule. This extension allows eligible hospitals additional time to submit requests for waivers and exceptions.

Submission of Electronic Patient Records to Beneficiary and Family Centered Care Quality Improvement Organizations (BFCC-QIOs)

FR pages 58977– 58985

Currently, QIOs are authorized to have access to the records of providers, suppliers, and practitioners under Medicare; and health care providers that submit Medicare claims must cooperate with QIO reviews. Providers must provide patient care and other pertinent data to the QIO when review information is being collected.

Beginning FFY 2021, CMS is adopting to mandate that providers and practitioners submit patient records to Beneficiary and Family Centered Care Quality Improvement Organizations (BFCC-QIOs) in an electronic format. This mandate would also update the procedures and reimbursement rates for patient records furnished to QIOs. Furthermore, CMS has adopted the definition of patient record as *“as all patient care data and other pertinent data or information relating to care or services provided to an individual patient, in the possession of the provider or practitioner, as requested by a BFCC-QIO for the purpose of performing one or more QIO functions.”*

As CMS is required to reimburse hospitals for the cost of providing patient records to the QIOs, they are adopting the following changes to the reimbursement requirements, applicable to all providers providing patient records for the purpose of QIO reviews:

- *“Patient records that are required to be provided to a QIO under § 476.78(b)(2) would need to be delivered in electronic format, unless a QIO approves a waiver. Providers and practitioners who lack the capability to submit patient records in an electronic format could submit patient records by facsimile or photocopying and mailing, after the QIO approves a waiver. Initial waiver requests by those providers that are required to execute a written agreement with a QIO would be expected to be made at the time the provider executes a written agreement with the QIO. Other providers and practitioners who are not required to execute a written agreement with a QIO would request a waiver by giving the QIO notice of their lack of capability to submit patient records in electronic format.*
- *Establish reimbursement rates of \$3.00 per patient record that is submitted to the QIO in electronic format and \$0.15 per page for requested patient records submitted by facsimile or by photocopying and mailing (plus the cost of first class postage for mailed photocopies), after a waiver is approved by the QIO.*
- *Apply those reimbursement rates to patient records submitted to a QIO in accordance with §§ 412.115, 413.355, 476.78, 480.111, and 484.265.”*

Revised Regulations to Account for, and Mandate, PRRB Electronic Filing

FR pages 58985 – 58989

The Provider Reimbursement Review Board (PRRB) is intended to furnish providers with way to resolve payment disputes arising from Medicare Part A final determinations.

To support the use of the electronic filing system, CMS adopting their updated definitions of “date of receipt” and “reviewing entity”. CMS also finalized that submissions to an electronic filing system are considered received on the date of electronic delivery. A new definition of “in writing or written” was also adopted, indicating that either of these terms refers to hard copy or electronic submission.

CMS is also adopting an update to 42 CFR 405.1857, related to subpoenas, so that it generally conforms to the technical changes that were finalized, as well as adding the following statement, *“If the subpoena request is being sent to a nonparty subject to the subpoena, then the subpoena must be sent by certified mail.”*

Finally, CMS finalized its amendment to the regulations at *“42 CFR 405.1843 (Parties to proceedings in a Board appeal) to make clear that parties to a Board appeal shall familiarize themselves with the instructions for handling a PRRB appeal, including any and all requirements related to the electronic or online filing of documents for future mandatory filing.”*

CMS will give 120 days’ notice prior to the mandatory use of the electronic filing system, rather than the proposed 60 days’ notice.

Medicare Bad Debt Policy

FR pages 58989 – 59006

Medicare allows for provider reimbursement for beneficiaries' unpaid deductible and coinsurance amounts for covered services reimbursed by Medicare based on reasonable cost or paid under a cost-based prospective payment system. In order to claim Medicare bad debt reimbursement, providers must first demonstrate that a reasonable effort to collect a non-indigent beneficiary's unpaid debts has been made. Under the Medicare bad debt policy, a "presumption of noncollectibility" states that if after reasonable effort has been made to collect a bill that the debt remains unpaid for more than 120 days from the date the first bill is mailed to the beneficiary, the debt may be deemed uncollectible and be designated as uncollectible bad debt.

Effective for cost reporting periods beginning on or before October 1, 2020, CMS is clarifying the distinction between indigent and non-indigent beneficiaries by defining a non-indigent beneficiary as *"a beneficiary who has not been determined to be categorically or medically needy by a State Medicaid Agency to receive medical assistance from Medicaid, and has not been determined to be indigent by the provider for Medicare bad debt purposes."*

Regarding the reasonable collection effort requirement for collection of Medicare bad debt, CMS has adopted a policy that it *"must involve the issuance of a bill to the beneficiary ... on or before 120 days after: (1) the date of the Medicare remittance advice; or (2) the date of the remittance advice from the beneficiary's secondary payer, if any; whichever is latest. A provider's reasonable collection effort also includes other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine ... collection effort. Additionally, a provider must maintain and, upon request, furnish documentation to its contractor that includes the provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients; the beneficiary's account history documents which show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.; and the beneficiary's file with copies of the bill(s) and follow-up notices."*

CMS also finalized *"that when the provider receives a partial payment within the minimum 120-day required collection effort period, the provider must continue the collection effort and the day the partial payment is received is day one of the new collection period. For each subsequent partial payment received during a 120-day collection effort period, the provider must continue the collection effort and the day the subsequent partial payment is received is day one of the new collection period."*

Also being finalized is the specification *"that a provider's effort to collect Medicare deductible and coinsurance amounts must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients. A provider's dissimilar debt collection practices for Medicare and non-Medicare patient accounts do not constitute a reasonable collection effort to claim reimbursement from Medicare for a bad debt..."*

A provider may use a collection agency to perform a reasonable collection effort on its behalf. The provider must ensure that the collection agency's collection effort is similar to the effort the collection agency puts forth to collect comparable amounts from non-Medicare patients. The collection agency's collection effort can include subsequent billings, collection letters, and telephone calls or personal contacts [and]... may include using or threatening to use court action to obtain payment.

The fee charged by the collection agency ... is not considered a Medicare bad debt... Medicare recognizes the fees the collection agency charges the provider as an allowable administrative cost. Where the collection agency does not follow the reasonable collection effort requirement, Medicare does not recognize the fees as an allowable administrative cost.

Collection accounts that remain at a collection agency ... cannot be claimed by the provider as a Medicare bad debt. When a collection agency obtains payment of an account receivable, the gross amount collected reduces the patient's account receivable by the same amount and must be credited to the patient's account. The collection fee deducted by the agency is charged to administrative costs."

CMS is finalizing requirements to document a provider's collection effort for non-indigent beneficiaries. Providers must maintain and furnish, upon request, verifiable documentation to its contractor which includes:

"(i) The provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare

patients,

(ii) The patient account history documents which show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.; and

(iii) The beneficiary's file with copies of the bill(s) and follow-up notices."

Regarding indigent beneficiaries, CMS is adopting their definition of an indigent non-dual eligible beneficiary as *"a Medicare beneficiary who is determined to be indigent by the provider and not eligible for Medicaid as categorically or medically needy."*

In response to public comments, CMS updated their proposal regarding the determination of an indigent non-dual eligible beneficiary. In order for a provider to determine if a beneficiary is an indigent non-dual eligible beneficiary, the provider:

"(1) Must not use a beneficiary's declaration of their inability to pay their medical bills or deductibles and coinsurance amounts as sole proof of indigence or medical indigence,

(2) Must take into account the analysis of both the beneficiary's assets (only those convertible to cash and unnecessary for the beneficiary's daily living) and income,

(3) May consider extenuating circumstances that would affect the determination of the beneficiary's indigence or medical indigence which may include an analysis of both the beneficiary's liabilities and expenses, if indigence is unable to be determined under (ii)(A)(2),

(4) Must determine that no source other than the beneficiary would be legally responsible for the beneficiary's medical bill, such as a legal guardian or State Medicaid program, and

(5) Must maintain and, upon request, furnish its Medicare contractor with the provider's indigence

1773 determination policy describing the method by which indigence or medical indigence is determined and all the verifiable beneficiary specific documentation which supports the provider's determination of each beneficiary's indigence or medical indigence."

CMS is adopting its proposal that once indigence is determined, bad debt can be deemed uncollectible without applying a collection effort, rather than the proposal to also include that the provider concludes that there has been no improvement in the beneficiary's financial status. However, *"unpaid deductible and coinsurance amounts without the provider's documentation of its determination of indigence will not be considered as allowable bad debts."*

For dual-eligible beneficiaries, CMS is finalizing *"that, effective for cost reporting periods beginning on and before the effective date of this rule, to be considered a reasonable collection effort, a provider that has furnished services to a dual eligible beneficiary must determine whether the State's Title XIX Medicaid Program (or a local welfare agency, if applicable) is responsible to pay all or a portion of the beneficiary's Medicare deductible and/or coinsurance amounts. To make this determination, the provider must submit a bill to its Medicaid/title XIX agency (or to its local welfare agency) to determine the State's cost sharing obligation to pay all or a portion of the applicable Medicare deductible and coinsurance. (This is effectuated by the provider submitting a bill to Medicare for payment and the MAC administering the payment process automatically 'crosses over' the bill to the applicable Medicaid/title XIX agency for determination of the State's obligation, if any, toward the cost sharing.)*

The provider must then submit to its contractor a Medicaid RA [Remittance Advice] reflecting the State's payment decision. Any amount that the State is obligated to pay, either by statute or under the terms of its approved Medicaid State plan, will not be included as an allowable Medicare bad debt, regardless of whether the State actually pays its obligated amount to the provider.

However, the Medicare deductible and/or coinsurance amount, or any portion thereof that the State is not obligated to pay, can be included as an allowable Medicare bad debt. A provider's failure to bill the State and produce to its Medicare contractor documentation, including the RA reflecting the State's verification that it processed a bill to determine its liability, will result in unpaid deductible and coinsurance amounts not being included as an allowable Medicare bad debt. Unpaid deductible and coinsurance amounts without collection effort documentation will not be considered as allowable bad debts."

CMS has finalized that bad debts (also known as "implicit price concessions"), charity, and courtesy allowances will represent reductions of revenue on cost reports.

Finally, CMS is adopting a modification to its proposal that, *“effective for cost reporting periods beginning on or after October 1, 2020, Medicare bad debts must not be written off to a contractual allowance account but must be charged to an uncollectible receivables account that results in a reduction in revenue.”*

####